

Health Technology Assessment in Poland) for orphan oncology drugs are based. The role of AHTAPol is to prepare for the Minister of Health recommendations on financing all medical technologies from public funds. Orphan oncology drugs undergo pharmacoeconomic evaluations and coverage decision processes similar to other molecules. AHTAPol's reimbursement recommendations are based on evidence of clinical benefit and efficacy/safety ratio, cost-effectiveness, costs and their impact on the payer's budget. **METHODS:** Among recommendations of AHTAPol published until the end of May 2011, we identified all related to orphan oncology drugs. Having categorized into types of recommendations then we analyzed rational for granted decision. **RESULTS:** Among 420 AHTAPol decisions analyzed, 32 (21,7%) applied to non-drugs technologies, 91 (21,7%) to health care programs and 297 (70,7%) to drugs technologies. Among 297 drugs recommendations only 15 (5%) was related to oncology orphan molecules. Granted were 10 (out of 15) positive recommendations. For 3 out of 15 drugs AHTAPol issued conditional recommendations (with restriction related to reducing the cost-effectiveness outcomes). Only two orphan oncology drugs were assessed negatively. In both cases main criteria on which recommendations were based refer to low clinical efficacy and safety. **CONCLUSIONS:** Neither cost-effectiveness nor costs and budget impact were significant arguments in negative recommendations of AHTAPol. As a matter of fact, lack of clinical efficacy and insufficient safety profile were the key issues for orphan oncology drugs negatively assessed by AHTAPol.

PHP93

REGIONAL DIFFERENCES AMONG METHADONE MAINTENANCE PROGRAMS IN SPAIN

Vieta A, Hurtado P

IMS Health, Barcelona, Barcelona, Spain

OBJECTIVES: Methadone maintenance programs (MMP) offer the best treatment for opioid dependence. In Spain, methadone hydrochloride is prepared as a magistral formulation. Despite the organization and the management of the MMP is in hands of the Delegación del Gobierno para el Plan Nacional sobre Drogas, each autonomous region (AR) is responsible for its planning and financing. The aim of this study was to identify planning MMP differences among AR in Spain. **METHODS:** A structured literature review on the IME, SciELO, Doyma, Medline, national and AR official bulletins and health web pages, and general and specialised press, up to July 1, 2010. **RESULTS:** Planning differences were found around four areas. First, in 13 AR the regional health department establishes the health care provision and legal framework for MMP, whereas in 4 AR this is a shared responsibility between health and social security regional departments. Second, three health care networks for the provision of MMP coexist in Spain. Andalusia has drug care centers, 6 AR specialized or mental health centers and 10 AR combine both structures. Third, in 11 AR methadone prescribing and dispensing is performed in one center, in 6 AR in separate centers and in Cantabria coincide both systems. Fourth, in the majority of AR a central laboratory or the hospitals elaborate the greater part of the methadone; however, in 2 AR it is elaborated in pharmacies and in 2 AR in the prescribing center. **CONCLUSIONS:** In Spain, patients are not always normalized into the health care system. Methadone provided in the MMP shows different elaboration, prescribing and dispensing processes across the different AR. This may lead to heterogeneity in the magistral formulation of methadone and patient access to it across the territory.

PHP94

ANALYSIS OF RESULTS OF THE REFERENCE PRICING OF TURKEY

Kockaya G, Uman N, Vural IM, Akbulut A, Ozsek E, Artiran G, Kerman S

General Directorate of Pharmaceuticals and Pharmacy, Ankara, Turkey

OBJECTIVES: IEGM (General Directorate of Pharmaceuticals and Pharmacy) is responsible for setting all human medicinal products prices. Reference pricing system is used for setting prices. Reference countries are reviewed annually and may be subject to certain alterations. The aim of this study is to show the distribution of reference countries which were used for reference pricing. **METHODS:** The price list of pharmaceuticals which was published by IEGM on 15.04.2011 was used for the analysis. Distribution of reference countries and prices were evaluated. **RESULTS:** Prices of 6251 jeneric and 3703 original products were set. 5283 of jenerics and 3306 of originals were in the positive list for reimbursement. Reference pricing was used for 2352 jenerics and 2281 originals. Prices of the remaining were set outside of reference pricing. 32 different countries were used for reference pricing. Italy was the most popular country for reference pricing (24.47%). Italy was followed by Spain (21.96%), Greece (19.69%), France (11.8%) and Portugal (8.7%). Even if Germany was not a reference country, Germany was used in 3.71% of pharmaceuticals. Other 25 countries were used by 13.29%. However the ranking was changed only in pharmaceuticals with prices above 200 Turkish Liras (TL) or original pharmaceuticals; Greece was the most popular country in these rankings by 27.85% and 24.25%, respectively. Italy was the most popular country for reference pricing in sub groups like generics, prices ranging between 0 and 50 TL, 50 and 100 TL, and 100 and 200 TL. **CONCLUSIONS:** It has been shown that Italy has the highest impact on the pricing of all pharmaceuticals in Turkey. Greece has the highest impact on the pricing of originals. Even if Germany was not a reference country, it has been seen that it affects pharmaceuticals more than other countries which were also not used for reference pricing.

PHP95

PAYER PERSPECTIVES ON EVIDENCE FOR FORMULARY DECISION MAKING IN THE UNITED STATES

Wang A, Baerwaldt T, Kuan R, Nordyke R, Halbert R

PriceSpective LLC, El Segundo, CA, USA

OBJECTIVES: The role that payers play in the pharmaceutical market has been increasing in prominence. Much research has focused on public payers and how drug reimbursement policies change in response to data from drug effectiveness studies. However, the commercial payer perspective has not been well researched. This study seeks to describe how U.S. commercial payers use different types of comparative evidence to make reimbursement and formulary placement decisions. **METHODS:** We recruited 20 US commercial payers who currently participate in or lead pharmaceutical and therapeutics committees for their plans. Our participants represent managed care organizations that cover a total of more than 95 million members. We conducted semi-structured qualitative interviews comprised of five representative scenarios and asked payers to rate how they value different study designs for each scenario. The interviews were transcribed, the responses were tabulated, and then analyzed for content. **RESULTS:** The reported value of the study designs differed between national and regional payers as well as between medical and pharmacy directors. National payers have more resources and are more likely to value and conduct retrospective analyses and decision modeling than regional payers. Pharmacy directors tend to favor retrospective analyses and medical directors value RCTs, pragmatic trials, and prospective non-experimental studies. Although RCTs were often the highest ranked study design, payers still found prospective non-experimental studies and retrospective analyses valuable for certain uses. Payers are currently unable to manage most oncology products beyond labeled indications due to political pressure to cover all drugs regardless of price. **CONCLUSIONS:** Payers value and utilize data from a broad range of study designs to inform formulary placement decisions. However, the disease state, market condition, and type of payer will influence what sort of comparative evidence is of the most value.

PHP96

MITIGATING EMERGENCY DEPARTMENT OVER-CROWDING UTILIZING FOCUSED OPERATIONS MANAGEMENT TOOLS

Schwartz D¹, Pliskin JS², Goldberg A³, Ronen B⁴

¹Ben-Gurion University of the Negev, Beer-Sheva, Israel, ²Ben Gurion University of the Negev, Beer-Sheva, Israel, ³Ben-Gurion University of the Negev, Beer Sheva, Israel, ⁴Tel Aviv University, Tel Aviv, Israel

OBJECTIVES: Emergency Department (ED) overcrowding (OC) is plaguing EDs worldwide with grave implications on patient and caregiver comfort and quality of care. Alleviating this problem tops agendas of governmental and professional agencies. Many contributing factors have been cited and many approaches have been tried, without widespread success. Focused Operations Management (FM) integrates novel managerial theories and practical tools [such as the theory of constraints (TOC) and the Pareto diagram] into a systematic approach, helping managers to analyze complex operational systems, find bottlenecks and root causes and finally, chart routes to improved throughput and quality. This approach has proved effective in the industry and service sectors, radically improving performance at little additional cost. The FM approach has never been implemented in the ED and could considerably enhance the management of its operations. In this first phase of the research, we use semi-structured interviews with experts, to identify potential high-yield interventions. **METHODS:** A review of the ED operations literature was performed to identify major ED operational challenges, metrics and alleviating measures. Semi-structured interviews with ED head nurses and managers, hospital administrators and Health ministry administrators were conducted. The interviews centered on validation of major challenges identified in the literature search and assessing potential utility of FM tools. **RESULTS:** The major challenges we identified included ED boarding, prolonged length of stay, unjustified ED utilization and slow access to specialist consults, lab tests and imaging studies. Of the FM tools presented to specialists, those assessed to be most promising were "the 'complete kit' concept and TOC methods to identify and alleviate bottle necks and to reduce 'work in progress'". **CONCLUSIONS:** Implementation of the novel FM management strategies has enhanced operations and performance in many industries and services. The ED is in dire need and a good candidate for the use of these tools.

PHP97

USE OF PAEDIATRIC "OBSERVATION STATUS" AND EFFECT ON IN-PATIENT ADMISSION RATE IN ACCIDENT AND EMERGENCY (A&E) DEPARTMENTS

Laokri S, Zhang WH, Ben Hamed N, Cohen L, De Wever A, Alexander S

Université Libre de Bruxelles, Brussels, Belgium

OBJECTIVES: To describe the use of paediatric "observation status" in the accident and emergency department (A&E). **METHODS:** A prospective survey was performed in 12 Belgian hospitals during 2 weeks straddling October and November 2010. All patients (<16 years) attending A&E were included. "Observation status" was defined when after the first medical evaluation, instead of hospitalization or home discharge, the situation required further observation of the patient. The clinicians in charge were asked at the start of the "observation" period to prognosticate whether the child would be discharged or admitted. **RESULTS:** Among 3220 children included in the study, the observation rate was 38.6%. The characteristics of these children were as follows. Median age: 5.0 years old (IQR: 1.7-11.3), boys: 53.5%. The median length of stay in A&E was 110 minutes (IQR: 65-175) and 14.3% were admitted as in-patient. The most common observations concerned orthopaedic, medical digestive and respiratory affections. The three main reasons for observation were additional procedures (69.0%), diagnostic determination (10.7%), and treatment testing (8.3%). Most of the observations (86.9%) were performed in a waiting room (not in a bed), 9.7% in an observation unit dedicated to children and

3.4% in an observation unit to adults. Only 4.1% of the observations satisfied the French paediatric short-stay definition (patient in a bed monitored hourly). Compared to the clinicians' prognosticated rate, 1.3% less children were admitted as in-patients. **CONCLUSIONS:** Despite the absence of financial and regulatory frame in Belgium, observation is a frequent modality of care. Observation helped to refine diagnosis and treatments and to reduce in-patient admission rate. However, with regards to the French guidelines less than 5% could be qualified as paediatric A&E short-stay. Flexible observation units should be recommended. **KEYWORDS:** Emergency, paediatrics, short-stay, observation status

PHP98

EXPLORING REGIONAL VARIATION IN TARIFFS/PUBLIC PRICES ACROSS AUTONOMOUS COMMUNITIES IN SPAIN: THE CASE OF DIAGNOSIS RELATED GROUPS AND ICD-9 DIAGNOSTIC CODES

Raluy M¹, De Cock E², Rovira J³, Gimenez E⁴, Albarracín MG⁵

¹United BioSource Corporation, London, London, UK, ²United BioSource Corporation, Barcelona, Spain, ³Barcelona, Spain, ⁴Boehringer Ingelheim, Sant Cugat del Valles, Barcelona, Spain, ⁵QUALIPLUS 77, SL, Barcelona, Barcelona, Spain

OBJECTIVES: Explore the variability of two sets of tariffs/public prices across Autonomous Communities (ACs) in Spain. **METHODS:** Tariffs/public prices for DRGs and ICD-9 procedure items from all 17 Spanish AC were extracted from official listings. For ICD-9, items appearing in at least 5 ACs were selected. Per item, variability in tariffs/public prices across ACs was measured using the coefficient of variation (CV) where greater CV indicates larger variability. Variability in DRG levels across ACs was assessed for a sub-set of 16 items. We developed a simple relative index whereby a tariff in a region was divided by the average tariff across all regions and then an overall index was computed as the simple mean of all items for each AC. **RESULTS:** Nine out of 17 ACs list DRGs. Navarra had the most complete list (681 items) and Catalonia the least complete (50 items). The lowest CV was for "spinal procedures" (DRG #4, mean: 10,335€, CV: 0.016, N=2) and the greatest for "abdominal interventions to neonates" (DRG 624, mean: 8139€, CV: 1248, N=6). On average, across the sub-set of 16 DRGs, Catalan tariffs were 63% below and La Rioja tariffs were 31% above the average across 9 ACs. ICD-9 tariffs were identified in 6 out of 17 ACs, and variability for 48 codes that were listed in at least 4 ACs was lowest for "repair of uterine support structures" (ICD-9 #69.2, mean: 1210€, CV: 0.07, N=4) and greatest for "local excision of breast lesion" (ICD-9 #85.21, mean: 710€, CV: 0.83, N=4). **CONCLUSIONS:** Results show great variability amongst AC tariff listings in Spain. Some ACs tend towards consistently higher or lower tariff levels, compared to the average across ACs. Differences are difficult to explain and suggest that tariffs and public prices do not reflect actual costs, but may be arbitrary estimates.

PHP99

REIMBURSING TELEMONITORING IN EUROPE: ARE PAYERS READY?

Flostrand S¹, Garde E², Toumi M³

¹Creativ-Ceutical, Paris, France, ²Sanofi, Paris, France, ³University Claude Bernard Lyon 1, Lyon, France

OBJECTIVES: As evidence and experience of telemonitoring grows, health care payers are confronted with multiple challenges to reimburse these new healthcare solutions. This study evaluated the current reimbursement systems in five European markets (France, Germany, Italy, Spain, and the UK) to determine readiness for telemonitoring and to identify changes required to permit telemonitoring to develop in the future. **METHODS:** To identify current telemonitoring funding, we reviewed the sources and mechanisms used to pay for pilot projects, and then reviewed national and regional health care funding systems to evaluate the readiness to finance telemonitoring. **RESULTS:** There are important differences in financing telemonitoring among European countries. While pilots exist in all countries, these are financed on a project basis from European Union, national or regional funds, outside regular healthcare budgets. Budget silos, disease reference group (DRG) changes and contractual funding are key barriers to payer readiness for telemonitoring. In Germany, only one telemonitoring DRG act is defined, while in France and Italy, defining telemonitoring acts for reimbursement is underway. In these countries, payers are reluctant to pay for the monitoring and alert service component. In Spain, regional authorities are advancing pilots at different speeds but system reforms have not yet been undertaken. Only in the UK, the English NHS has moved from pilots to deployment through financing at the Primary Care Trust level. **CONCLUSIONS:** European reimbursement systems do not yet accommodate telemonitoring, and pilots and device purchases will not sustain this therapeutic solution. To enable telemonitoring, payers need to establish new codes and rules to pay for telemonitoring acts by health care professionals, and decide how to pay for the most complex element: the monitoring and alert service component. Options include: no reimbursement (the current option), a periodic fixed fee or capitation. Any option requires careful framing and the benefits of telemonitoring need further evaluation.

PHP100

DID IQWiG'S DRUG APPRAISALS IN CONNECTION WITH G-BA'S DIRECTIVES CHANGE PRESCRIBING BEHAVIOR OF GERMAN PHYSICIANS?

Valentin M¹, Neises G², Salek S³

¹Fresenius University of Applied Science, Idstein, Germany, ²ABDA, Berlin, Germany, ³Cardiff University, Cardiff, UK

OBJECTIVES: To assess the impact of different formats of G-BA's (Federal Joint Committee) directives had on the prescription behavior of health care professionals (HCPs) prior to the introduction of the AMNOG legislation (i.e. Directives restructuring the German pharmaceutical market). **METHODS:** A retrospective study of the IQWiG's (Institute for Quality and Efficiency in Healthcare) review of pharmaceutical products covered by a G-BA directive during a 5-year period (2005-2010).

An event list reporting the interaction of G-BA, IQWiG and BMG (German Minister of Health) was compiled by systematic searches of official websites. Regression analyses retrieved from IMS data bases (Intercontinental Marketing Services) were conducted defining a 95% confidence interval. Time points where actual sales exceeded or deceased this confidence interval were reconciled with the list of events concluding if and what kind of events had impacted unit sales. **RESULTS:** G-BA required a mean of 1304 days to generate a directive followed by 567 days required by IQWiG to complete its review. IQWiG achieved a mean output of 15 projects per year, which is half of what NICE achieved in the same period. The format of the final directive had a strong influence on the overall review. These findings indicate that G-BA's directives did not influence the annual number of prescriptions during the five year period. **CONCLUSIONS:** The new set of laws – commonly known as AMNOG is targeting two important weaknesses of the previous systems, which are clearly identified by this study. Thus, clear ambitious timelines should be defined, especially for the most time consuming review stages, namely completion of the report plan and adherence to the principle of evidence based medicine for all reviews.

PHP101

BIOSIMILARS ARE NOT GENERICS FROM PAYER PERSPECTIVE

Shepelev J¹, Rauland M², Krattiger C³

¹GfK HealthCare, London, UK, ²GfK HealthCare, Nürnberg, Germany, ³GfK Research Matters, Basel, Switzerland

OBJECTIVES: To review the barriers and opportunities in market access for biosimilars. **METHODS:** Both primary & secondary research were used in this study. Primary research was conducted with payers, physicians, pharmaceuticals and biosimilar manufacturers. **RESULTS:** The US and EU are currently the largest consumers of biologics in the world; however, other markets are expected to see strong growth in their use of biologics over the next few years. Although many biologics are expected to go off-patent in the next few years, (thereby creating an attractive opportunity for biosimilars); the complex structure of biologics makes the manufacturing process of biosimilars extremely difficult, and with EU legislation currently requiring phase I-III clinical trials to be conducted for all new biosimilars the developmental costs and barriers to entry of biosimilars are high. With respect to the costs per treatment, the price of biologics are significantly higher than for small molecules creating a use-limiting factor in many markets; for this reason biosimilars are recognised by payers and physicians as being cost-effective in the sense of being able to provide the same treatment but at a lower cost (20% cheaper). However, payers confirmed that cost-saving alone will not ensure access for biosimilars and physicians are hesitant to adopt biosimilars due to safety and efficacy concerns. **CONCLUSIONS:** With the use of biologics rapidly increasing, patent expiries expected to occur in the near future and the low numbers of competitors, companies are presented with a new and attractive market with the production of biosimilars. Although there are several challenges to entering the market (including the intense approval process) biosimilars are recognized and are treated differently from generics by payers. With drug costs increasing and concerns over the safety and efficacy of biosimilars, reduced costs of biosimilars together with clinical reassurance will enable broader acceptance and usage of biosimilars in most markets.

PHP102

BIOSIMILARS: PRICING & REIMBURSEMENT IN GERMANY: KEY INSIGHTS FROM SICKNESS FUNDS

Chaudhari SD, Bache B

PAREXEL International, Uxbridge, Middlesex, UK

OBJECTIVES: While the European biosimilars market is still in its infancy, these products are facing tough market access conditions and have yet to match the success of small-molecule generics. With the increasing cost consciousness of the payers and potentially safety concerns, it is imperative to explore the key pricing and reimbursement drivers and barriers for biosimilars from the payer-lens. In addition, the research aims to provide insights into strategies for their successful 'market access' in the German healthcare system. **METHODS:** This research was based on a combination of secondary and primary research to evaluate the key success factors for biosimilars. Secondary research of published data such as G-BA's assessment of biosimilars, current policies, sector-specific research articles contributed towards a framework to understand the key factors affecting payer's attitudes towards biosimilars, which was then validated through a telephone survey of 10 sickness funds in 2011. **RESULTS:** A multitude of factors determine price sustainability for biosimilars in Germany. The attitudes of sickness funds toward biosimilars vary, which affect price dynamics as well as the cost containment measures to encourage/inhibits its use. While the use and prescribing of biosimilars are subject to quotas and guidelines encouraging its use, some sickness funds' focus on price is moderated by concerns about the safety of biosimilars. Overall, in order to provide access to these products, payers are increasingly raising data requirements. **CONCLUSIONS:** There exists significant inter-payer variability in the extent of inter-changeability and data expectation from future biosimilars. Payer expectations vary, based on the stage of the disease/indications, the level of unmet need, and the number of available alternatives. In a climate of increasing pricing concerns, securing marketing approval is no longer the end of the road for biosimilars. Hence, unlike generics, biosimilars cannot be merely 'sold' but need to be 'marketed'.

PHP103

GLOBAL HEALTH CARE REFORMS AND PRICING, ACCESS AND HEALTH OUTCOMES STRATEGY